



PATENT

Attorney Docket No.: BEAU 4 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.: 10/049,992

Group Art Unit: 1646

371 (c) Date: October 07, 2002

Applicant: Beaulieu, A. et al.

Examiner: C.T. Ostrup/F.Krass
handling related case

Title: SOLID WOUND HEALING
FORMULATIONS CONTAINING FIBRONECTIN

CERTIFICATE OF HAND DELIVERY

U.S. Patent and Trademark Office
2011 South Clark Place
Customer Window, Mail Stop Non-Fee Amendment (IDS)
Crystal Plaza Two, Lobby, Room 1B03
Arlington, Virginia 22202

Sir:

I hereby certify that the following documents:

1. Supplemental Information Disclosure Statement Cover Letter dated March 25, 2004 -- Two (2) pages;
2. Form PTO-1449 (modified) -- Seven (7) pages; and
3. References Nos. 39-106.

are being hand-filed with the United States Patent and Trademark Office at the

Customer Window, 2011 South Clark Place, Crystal Plaza Two, Lobby, Room 1B03

Arlington, Virginia 22202 on March 30, 2004

Sam Zaghmout

O. M. (Sam) Zaghmout (Reg. No. 51286)
8509 Kernon Ct
Lorton VA US 22079
703-550-1968



Attorney Docket No.: BEAU 4 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.: 10/049,992

Group Art Unit: 1646

371 (c) Date: October 07, 2002

Applicant: Beaulieu, A. et al.

Examiner: C.T. Ostrup/F.Krass
handling related case

Title: SOLID WOUND HEALING
FORMULATIONS CONTAINING FIBRONECTIN

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

U.S. Patent and Trademark Office
2011 South Clark Place
Customer Window, Mail Stop Non-Fee Amendment (IDS)
Crystal Plaza Two, Lobby, Room 1B03
Arlington, Virginia 22202

Sir:

Pursuant to 37 CFR § 1.56, Applicants request that the references cited in the accompanying Form PTO-1449 containing references 39-106 to be considered by the Examiner in the above-identified application and made of record therein. Copies of the cited references are enclosed.

The references submitted in this Supplemental Information Disclosure Statement were listed in the bibliographies of Provisional Application Serial Numbers 60/149,958, filed August 20, 1999 and Provisional Application Serial Number 60/182,412, filed February 14, 2000. If a reference in the bibliographies was previously cited in this case, the reference was not duplicated in the accompanying Form PTO-1449.

Attorney Docket No.: BEAU 4 US

If the Examiner needs additional information or would like to receive the enclosed information in a different format, the Examiner is requested to call or e-mail the undersigned.

The Information Disclosure Statement submitted herewith is being filed before the mailing of a first Office Action on the merits.

The Commissioner is hereby authorized to charge any additional fees, or to credit any overpayment, to Deposit Account No. 15-0699. A duplicate copy of this sheet is attached.

Respectfully submitted,

Date: March 25, 2004



Manette Dennis (Reg. No. 30,623)
Ostrager Chong & Flaherty LLP
825 Third Avenue 30th Floor
New York, New York 10022
Tel.: 212 826-6565
Fax: 212 826-5909
mdennis@ocflaw.com



Please type a plus sign (+) inside this box → +

PTO/SB/08A (10-96)

Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/049,002
				Filing Date	October 07, 2002
				First Named Inventor	A. Beaulieu
				Group Art Unit	1646
				Examiner Name	Ostrup, Clinton T. (related case)
Sheet	1A	of	7-A	Attorney Docket Number	Beau 4 US

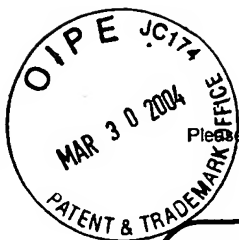
OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	39	SMAGLIK, P. "Promise and Problems Loom for Stem Cell Gene Therapy," The Scientist (1999), page 14, vol. 13, no. 15 and larger print version from The Scientist website	
	40	BROWN, C.D. et al., "A Review of Topical Agents for Wounds and Methods of Wounding-- Guidelines for Wound Management, Journal of Dermatology Surgery and Oncology, 1993, pages 732-737, vol. 19	
	41	"Carbopol® Resins --GC-67" BF Goodrich, 1990, Cleveland, OH	
	42	DORAN, J.E. et al., "Cold Insoluble Globulin-Enhanced Phagocytosis of Gelatinized Targets by Macrophage Monolayers: A Model System," Journal of the Reticuloendothelial Society, 1980, pages 471-483, vol. 27, no. 5	
	43	EDWARDS, C.A. et al., "Tri (n-Butyl) Phosphate/Detergent Treatment of Licensed Therapeutic and Experimental Blood Derivatives," Vox Sang. 1987, pages 53-59, vol. 52	
	44	HYNES, R. O., Fibronectins, 1990, Springer-Verlag	
	45	MOLNAR, J et al., "Definition of Fibronectin-mediated Uptake of Gelatinized Latex by Liver Slices and Macrophages," Biochimica et Biophysica Acta, 1987, pages 326-337, vol. 930	
	46	PIET, M.P.J. et al., "The Use of Tri (N-butyl) phosphate Detergent Mixtures to Inactivate Hepatitis Viruses and Human Immunodeficiency Virus in Plasma and Plasma's Subsequent Fractionation," 1990, Transfusion, pages 591-598, Vol 30., No. 7	
	47	RADSEVICH, M., "Research and Development Commitments in an Integrated Plasma Collection and Plasma Fractionation Environment," Seminars in Thrombosis and Hemostasis, 1998, pages 157-161, Vol. 24, No. 2	
	48	REGNAULT, V. et al., "Preparation de fibronectine humaine de haute purete fonctionnellement active," Revue Francaise de Transfusion et Immuno-hematologie, pages 19-34, 1988, Vol. 31, No. 1 (English Abstract)	
	49	RUOSLAHTI, E. et al., "Fibronectin Purification, Immunochemical Properties, and Biological Activities," Methods in Enzymology, 1982, pages 803-831, vol. 82	

Examiner Signature	Date Considered
---------------------------	------------------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



Please type a plus sign (+) inside this box → ☐

PTO/SB/08A (10-96)

Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known	
		Application Number	10/049,992
		Filing Date	October 07, 2002
		First Named Inventor	A. Beaulieu
		Group Art Unit	1646
		Examiner Name	Ostrup, Clinton T. (related case)
Sheet 2A of 7-A	Attorney Docket Number	Beau 4 US	

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	50	HARAHAP, M., "Differential Diagnosis of Leg Ulcers," Clinics in Dermatology, 1990, pages 1-3, Vol. 8, No. 3/4	
	51	HARAHAP, M., "Leg Ulcers Caused by Bacterial Infections," Clinics in Dermatology, 1990, pages 49-65, Vol. 8, No. 3/4	
	52	PHILLIPS, T.J. et al., "Leg Ulcers," Journal of the American Academy of Dermatology, 1991, pages 965-87, Vol 25, No. 6	
	53	EAGLSTEIN, W. H., "Effect of Occlusive Dressings on Wound Healing," Clinics in Dermatology, 1984, pages 107-111, Vol. 2, No. 3	
	54	EAGLSTEIN, W.H., "Current Wound Management: A Symposium," Current Wound Management, 1984, pages 134-142, Vol. 2, No. 3	
	55	EAGLSTEIN, W.H. et al., "Effect of Topically Applied Agents on Healing Wounds," Clinics in Dermatology, 1984, pages 112-115, Vol. 2, No. 3	
	56	MULDER, G.D., "Clinical Protocols for Studying Wound Healing," Clinical Materials, 1991, pages 251-255, Vol. 8	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



Please type a plus sign (+) inside this box → ☐

PTO/SB/08A (10-96)

Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known			
		Application Number	10/049,992		
		Filing Date	October 07, 2002		
		First Named Inventor	A. Beaulieu		
		Group Art Unit	1646		
		Examiner Name	Ostrup, Clinton T. (related case)		
Sheet	3A	of	7-A	Attorney Docket Number	Beau 4 US

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	57	SINGER, A. J. et al., "Cutaneous Wound Healing," New England Journal of Medicine, 1999, pages 738-746, Vol. 341, No. 10	
	58	CLARK, R. A. F., "Potential Roles of Fibronectin in Cutaneous Wound Repair," Arch. Dermatol., 1988, pages 201-206, Vol. 124	
	59	NORRIS, D. A. et al., "Fibronectin Fragments(s) are Chemotactic for Human Peripheral Blood Monocytes," Journal of Immunology, 1982, pages 1612-1618, Vol. 129, No. 4	
	60	CLARK, R. A. F. et al., "Cryptic Chemotactic Activity of Fibronectin for Human Monocytes Resides in the 120-kDA Fibroblastic Cell-binding Fragment," Journal of Biological Chemistry, 1988, pages 12115-12123, Vol. 263, No. 24	
	61	ALI, I. U. et al., "Effects of LETS Glycoprotein on Cell Motility," Cell, 1978, pages 439-446, Vol. 14	
	62	POSTLETHWAITE, A. E. et al., "Induction of Fibroblast Chemotaxis by Fibronectin: Localization of the Chemotactic Region to a 140,000-Molecular Weight Non-Gelatin-binding Fragment," J. Exp. Med., 1981, pages 494-499, Vol. 153	
	63	SEPPA, H. E. J. et al., "The Cell Binding Fragment of Fibronectin is Chemotactic for Fibroblasts," Cell Biology International Reports, 1981, pages 813-819, Vol. 5, No. 8	
	64	BOWERSOX, J. C. et al., "Chemotaxis of Aortic Endothelial Cells in Response to Fibronectin," Cancer Research, 1982, pages 2547-2551, Vol. 42	
	65	O'KEEFE, E. J. et al., "Production of Soluble and Cell-Associated Fibronectin by Cultured Keratinocytes," Journal of Investigative Dermatology, 1984, pages 150-155, Vol. 82, No. 2	
	66	MOSESSON, M. W. et al., "The Cold-insoluble Globulin of Human Plasma," Journal of Biological Chemistry, 1970, pages 5728-5736, Vol. 245, No. 21	
	67	WEISS, E. et al., "Un-Cross-Linked Fibrin Substrates Inhibit Keratinocyte Spreading and Replication: Correction with Fibronectin and Factor XIII Cross-Linking," Journal of Cellular Physiology, 1998, pages 58-65, Vol. 174	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



Please type a plus sign (+) inside this box → ☐

PTO/SB/08A (10-96)

Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Complete if Known		
			Application Number	10/049,992	
			Filing Date	October 07, 2002	
			First Named Inventor	A. Beaulieu	
			Group Art Unit	1646	
			Examiner Name	Ostrup, Clinton T. (related case)	
Sheet	4A	of	7-A	Attorney Docket Number	Beau 4 US

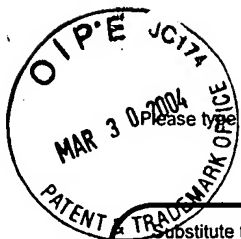
OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	68	CZOP, J. K., "Phagocytosis of Particulate Activators of the Alternative Complement Pathway: Effects of Fibronectin," Advances in Immunology, 1986, pages 361-398, Vol. 38	
	69	BEVILACQUA, M. P. et al., "Receptors for Cold-Insoluble Globulin (Plasma Fibronectin) on Human Monocytes," J. Exp. Medicine, 1981, pages 42-60, vol. 153	
	70	POMMIER, C. G. et al., "Plasma Fibronectin Enhances Phagocytosis of Opsonized Particles by Human Peripheral Blood Monocytes," J. Exp. Medicine, 1983, pages 1844-1854, Vol. 157	
	71	BROWN, E. J., "The Role of Extracellular Matrix Proteins in the Control of Phagocytosis," Journal of Leukocyte Biology, 1986, pages 579-591, Vol. 39	
	72	GRINNELL, F. et al., "Initial Adhesion of Human Fibroblasts in Serum-Free Medium: Possible Role of Secreted Fibronectin," Cell, 1979, Pages 117-129, Vol. 17	
	73	TAKASHIMA, A. et al., "Fibronectin-Mediated Keratinocyte Migration and Initiation of Fibronectin Receptor Function in Vitro," Journal of Investigative Dermatology, 1985, pages 304-308, Vol. 85	
	74	CLARK, R. A. F. et al., "Fibronectin, as Well as Other Extracellular Matrix Proteins, Mediate Human Keratinocyte Adherence," Journal of Investigative Dermatology, 1985, pages 378-383, Vol. 84	
	75	O'KEEFE, E. J. et al., "Spreading and Enhanced Motility of Human Keratinocytes on Fibronectin," Journal of Investigative Dermatology, 1985, pages 125-130, Vol. 85	
	76	MACARAK, E. J. et al., "Adhesion of Endothelial Cells to Extracellular Matrix Protein," Journal of Cellular Physiology, 1983, pages 76-86, Vol. 116	
	77	PALOTIE, A. et al., "Components of Subendothelial Aorta Basement Membrane," Laboratory Investigation, 1983, pages 362-370. Vol. 49, No. 3	
	78	CLARK, R. A. F. et al., "Either Exogenous or Endogenous Fibronectin Can Promote Adherence of Human Endothelial Cells," J. Cell. Sci., 1986, pages 263-280, Vol. 82	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



Please type a plus sign (+) inside this box →



PTO/SB/08A (10-96)

Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application Number	10/049,992
				Filing Date	October 07, 2002
				First Named Inventor	A. Beaulieu
				Group Art Unit	1646
				Examiner Name	Ostrup, Clinton T. (related case)
Sheet	5A	of	7-A	Attorney Docket Number	Beau 4 US

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	79	HORSBURGH, C. R. et al., "Lymphokines and Platelets Promote Human Monocyte Adherence to Fibrinogen and Fibronectin in Vitro," Journal of Leukocyte Biology, 1987, pages 14-24, Vol. 41	
	80	GRINNELL, F. et al., "Distribution of Fibronectin During Wound Healing in Vivo," The Journal of Investigative Dermatology, 1981, pages 181-189, Vol. 76, No. 3	
	81	REPESH, L. A. et al., "Fibronectin Involvement in Granulation Tissue and Wound Healing in Rabbits," The Journal of Histochemistry and Cytochemistry, 1982, pages 351-358, Vol. 30, No. 4	
	82	CLARK, R. A. F. et al., "Fibronectin and Fibrin Provide a Provisional Matrix for Epidermal Cell Migration During Wound Reepithelialization," The Journal of Investigative Dermatology, 1982, pages 264-269, Vol. 79, No. 5	
	83	CLARK, R. A. F. et al., "Blood Vessel Fibronectin Increases in Conjunction with Endothelial Cell Proliferation and Capillary Ingrowth During Wound Healing," The Journal of Investigative Dermatology, 1982, pages 269-276, Vol. 79, No. 5	
	84	HEDMAN, K. et al., "Isolation of the Pericellular Matrix of Human Fibroblast Cultures," J. Cell Biology, 1979, pages 83-91, Vol. 81	
	85	HEDMAN, K. et al., "Structure of the Pericellular Matrix: Association of Heparan and Chondroitin Sulfates with Fibronectin-Procollagen Fibers," Cell, 1982, pages 663-671, Vol. 28	
	86	HEDMAN, K. et al., "Integrity of the Pericellular Fibronectin Matrix of Fibroblasts is Independent of Sulfated Glycosaminoglycans," The EMBO Journal, 1984, pages 581-584, Vol. 3, No. 3	
	87	CARTER, W. G., "The Role of Intermolecular Disulfide Bonding in Deposition of GP140 in the Extracellular Matrix," Journal of Cell Biology, 1984, pages 105-114, Vol. 99	
	88	CLARK, R. et al., "TGF-β1 Stimulates Cultured Human Fibroblasts to Proliferate and Produce Tissue-Like Fibroplasia: A Fibronectin Matrix-Dependent Event," Journal of Cellular Physiology, 1997, pages 69-80, Vol. 170	
	89	NAKADA, M. et al., "Efficacy of Exogenous Fibronectin in Wound Healing in Malnourished Rats," Journal of Pediatric Surgery, 1998, pages 1699-1702, Vol. 33, No. 11	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



Please type a plus sign (+) inside this box → +

PTO/SB/08A (10-96)

Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known			
				Application Number		10/049,992	
				Filing Date		October 07, 2002	
				First Named Inventor		A. Beaulieu	
				Group Art Unit		1646	
				Examiner Name		Ostrup, Clinton T. (related case)	
Sheet	6A	of	7-A	Attorney Docket Number		Beau 4 US	

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	90	CHENG, C.Y. et al., "Fibronectin Enhances Healing of Excised Wounds in Rats," Arch. Dermatol., 1988, pages 221-225, Vol. 124	
	91	KONO, I. et al., "Beneficial Effect of Topical Fibronectin in Patients with Keratoconjunctivitis Sicca of Sjogren's Syndrome," Journal of Rheumatology, 1985, pages 487-489, Vol. 12	
	92	NISHIDA, T. et al., "Fibronectin Enhancement of Corneal Epithelial Wound Healing of Rabbits In Vivo," Arch. Ophthalmol., 1984, pages 455-456, Vol. 102	
	93	WHITE, H., "A Heteroskedasticity-Consistent Covariance Matrix Estimator and a Direct Test for Heteroskedasticity," Econometrica, 1980, pages 817-838 Vol. 48, Issue 4	
	94	COLLETT, D., "Model Checking in the Proportional Hazards Model," Chapter 5 in Modelling Survival Data in Medical Research, 1994, 1 st edition, Chapman & Hall, London; New York	
	95	KATZ, M.H. et al., "Proportional Hazards (Cox) Regression," Journal of General Internal Medicine, 1993, pages 702-711, Vol. 8	
	96	SCHEMPER, M., "Cox Analysis of Survival Data with Non-Proportional Hazard Functions," Statistician, 1992, pages 455-465, Vol. 41, Issue 4	
	97	GREENLAND, S., "Modeling and Variable Selection in Epidemiologic Analysis," American Journal of Public Health, 1989, pages 340-349, Vol. 79, No. 3	
	98	ROBINS, J. M. et al., "The Role of Model Selection in Causal Inference from Nonexperimental Data," American Journal of Epidemiology, 1986, pages 392-402, Vol. 123, No. 3	
	99	FALANGA, V., "Care of Venous Leg Ulcers," Ostomy/Wound Management, 1999, pages 33S-43S, Vol 45 (Suppl. 1A)	
	100	MARGOLIS, D. et al., "Risk Factors Associated with the Failure of a Venous Leg Ulcer to Heal," Arch. Dermatol., 1999, pages 920-926, vol. 135	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



Please type a plus sign (+) inside this box → ☐

PTO/SB/08A (10-96)

Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 7A of 7-A

Complete if Known

Application Number	10/049,992
Filing Date	October 07, 2002
First Named Inventor	A. Beaulieu
Group Art Unit	1646
Examiner Name	Ostrup, Clinton T. (related case)
Attorney Docket Number	Beau 4 US

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	101	MARSTON, W. A. et al., "Healing Rates and Cost Efficacy of Outpatient Compression Treatment for Leg Ulcers Associated with Venous Insufficiency," J. Vasc. Surgery, 1999, pages 491-98, Vol. 30, No. 3	
	102	OLIN, J. W. et al., "Medical Costs of Treating Venous Stasis Ulcers; Evidence from a Retrospective Cohort Study," Vascular Medicine, 1999, pages 1-7, Vol. 4	
	103	PHAN, T.-M. M. et al., "Topical Fibronectin in the Treatment of Persistent Corneal Epithelial Defects and Trophic Ulcers," American Journal of Ophthalmology, 1987, pages 494-501, Vol. 104	
	104	FLEISS, J., Statistical Methods for Rates and Proportions, 1981, pages 38-42, John Wiley and Sons, New York	
	105	LACHIN, J. M. et al., "Evaluation of Sample Size and Power for Analyses of Survival with Allowance for Nonuniform Patient Entry, Losses to Follow-Up, Noncompliance, and Stratification," Biometrics, 1986, pages 507-519, Vol. 42, issue 3	
	106	HOSMER, D. et al., Applied Logistic Regression, 1989, pages 149-170, John Wiley and Sons, New York	

Examiner
Signature

Date
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.